THE HONORABLE RICHARD A. JONES

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

FAIRHAVEN HEALTH, LLC, Plaintiff, v. BIO-ORIGYN, LLC, JOANNA ELLINGTON, AKA JOANNA CLIFTON, AND DENNIS CLIFTON, Defendant.	Case No. 2:19-cv-01860-RAJ **ORDER**

I. INTRODUCTION

This matter is before the Court on Fairhaven's ("Plaintiff") Motion for a More Definite Disclosure of Infringement Contentions and Stay, and Motion to Strike ("Motion") (Dkt. # 102). Having considered the submissions of the parties, the relevant portions of the record, and the applicable law, the Court **DENIES** the Motion.

II. BACKGROUND

This case concerns Plaintiff's request for a declaratory judgment of noninfringement with regard to its BabyIt products. Plaintiff alleges that it paid sales-based royalties to BioOrigyn, Joanna Ellington, and Dennis Clifton ("Defendants") on BabyIt products pursuant to a patent license from Defendants. Plaintiff further alleges that it entered into this license based on Defendants' representations that the BabyIt

products practiced, and were therefore protected by, one or more claims of U.S. Patent No. 7,838,509 (the "509 patent"). Plaintiff seeks the return of royalty and other payments because the BabyIt products never practiced the claims of the '509 patent. Dkt. # 102 at 2.

In January 2022, Defendants filed an Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Amended Complaint, in which Defendants request a declaratory judgment that the BabyIt product infringes on one or more claims of the '509 patent. Dkt. # 75 at 33. On April 8, 2022, pursuant to Local Patent Rule ("LPR") 120, Defendants served their infringement contentions ("Infringement Contentions") as to the '509 patent on Plaintiff. The Contentions accuse all BabyIt products that were made, used, sold, offered for sale, or imported during the life of the '509 patent of infringement. One month later, Plaintiff filed the instant motion, alleging several defects in Defendants' contentions. At the parties' request, on June 6, 2022, the Court stayed all deadlines related to claim construction pending the resolution of the instant motion. Dkt. # 113.

III. DISCUSSION

Plaintiff Fairhaven argues that Defendants' Contentions fail to provide reasonable notice to Plaintiff as to why Defendants believe the BabyIt products practice the claims of the '509 patent. Dkt. # 102 at 2. Plaintiff allege several specific deficiencies in Defendants' contentions: 1) they contain non-scientific marketing materials, information concerning an unrelated product and an unsold pilot batch, and test data derived from two lots of BabyIt products that were either expired or a new formulation; and (2) while Defendants allege indirect infringement and infringement under the doctrine of equivalents, they provide only bare bones recitations and fail to connect these allegations with the accused products. *Id.* at 2-3. Plaintiff requests that the Court order Defendants to serve amended contentions, stay discovery related to all

BabyIt products until amended contentions are served, and strike portions of Defendants' Contentions that allege indirect infringement and infringement under the doctrine of equivalents, references to marketing materials, and information related to the BabyDance product and several specific lot numbers. *Id.* at 4.

Defendant, on the other hand, argues that Plaintiff's motion is procedurally improper under Federal Rule of Civil Procedure 12, that Plaintiff did not properly engage in a robust meet and confer process prior to filing the motion, and that the Contentions sufficiently identify the accused device and where each element of each asserted claim is found because the contentions accuse *all* BabyIt that was made, used, sold, offered for sale, or imported during the life of the '509 patent of infringement. Dkt. # 107 at 4-8.

a) Legal Standard

The Local Supplemental Patent Rules for the Western District of Washington ("LPR") require that "within 15 days of the Scheduling Conference or, if there is no Scheduling Conference, entry of the case schedule, a party claiming infringement shall serve on all parties a 'Disclosure of Asserted Claims and Infringement Contentions.'" LPR 120. The disclosure shall include: (a) a claim of each patent that is allegedly infringed by each party; (b) each accused apparatus, product, device, process, method, act, or other instrumentality for each asserted claim; (c) a chart identifying specifically where each element of each asserted claim is located within each accused instrumentality for each asserted claim; (d) for indirect infringement, a description of the acts of the alleged indirect infringer that induced the direct infringement by a third party; (e) whether each limitation of each asserted claim is alleged to be literally present or present under the doctrine of equivalents in the accused instrumentality; and (f) the priority date to which each asserted claim is allegedly entitled, if applicable. *See* LPR 120.

The purpose of the Western District of Washington's local patent rules is to "require parties to state early in the litigation and with specificity their contentions with respect to infringement and invalidity." *0912139 B.C. Ltd. v. Rampion USA Inc.*, No. C18-1464JLR, 2019 WL 3082290, at *1 (quoting *02 Micro Int'l Ltd. v. Monolithic Power Systems, Inc.*, 467 F.3d 1355, 1359 (Fed. Cir. 2006)). Infringement contentions may only be amended "by order of the Court upon a timely showing of good cause." LPR 124. Given the similarities between the local patent rules of this District and those of the Northern District of California, cases from that district "offer helpful standards" that may be applied in this matter. *Int'l Bus. Mach. Corp. v. Zillow Grp., Inc.*, No. C20-851 TSZ, 2020 WL 3266220, at *1 (W.D. Wash. June 17, 2020). "District courts have broad discretion to enforce local patent rules." *Rampion*, 2019 WL 3082290, at *1.

b.) Identification of the Accused Device

Plaintiff argues that Defendants' failure to identify the accused products by lot number flouts the Local Rules. The Local Rules require that each product "be identified by name or model number, if known." LPR 120(b). The parties disagree as to whether Defendants know the lot numbers, with Plaintiff claiming that "all lot number information and details" are "already in Defendants' possession," and Defendants asserting that it was Plaintiffs who manufactured and sold the accused products and have such information. *See* Dkt. # 107, 7. Additionally, Defendants essentially argue that Plaintiffs have overstated the significance of the lot numbers with regard to the Infringement Contentions, arguing that lot numbers correspond to specific dates and specific production runs, but do not indicate that "the products are meaningfully different or that manufacturing specifications differ from batch to batch." Dkt. # 107 at 8. The Court finds Defendants' argument that the Local Rules do not require them to identify all accused products by lot numbers persuasive. While the parties disagree on which party has the full and precise details on each production run—and therefore, lot

number—of BabyIt, this information should soon be known to both parties though ongoing discovery. *See Genuine Enabling Tech. LLC v. Nintendo Co., Ltd.*, No. C19-00351-RSM, 2019 WL 3779867, at *5 (W.D. Wash. Aug. 12, 2019) ("Allowing [Plaintiff] the opportunity to glean more information through discovery accords with this District's case law, which recognizes that the Local Patent Rules require disclosures before the completion of claim discovery.") (citing *Recognicorp, LLC v. Nintendo Co.*, No. C12-1873RAJ, 2013 WL 2099518, at *2 (W.D. Wash. May 8, 2013)). Because Defendants have identified "each BabyIt product made, used, sold, and/or offered for sale by or on behalf of Fairhaven," along with three lot numbers that Defendants claim are currently available to them, Defendants have met the requirements of LPR 120(b), which require them to identify accused products "by name or model number, if known."

Further, Plaintiff's argument that Defendants have flouted LPR 120(c) because Defendants have treated "BabyIt as a single accused device" and Defendants' claim charts do not match up with their alleged evidence is similarly unavailing. Defendants correctly note that "a separate claim chart for each accused product is not mandatory," particularly where each accused product allegedly infringes in the same way. *Finjan, Inc. v. Proofpoint, Inc.*, 2015 WL 1517920, at *3 (N.D. Cal. Apr. 2, 2015) (applying local patent rules of Northern District of California). Defendants allege that all BabyIt products, "[r]egardless of lot numbers," Dkt. # 107 at 8, allegedly infringe the '509 patent because of several characteristics that they all contain: "a balanced salt solution," a "lubricious compound" that is "nonspermicidal" and is "able to lubricate vaginal mucosa," and contains "arabinogalactan" and "carbomer" in the lubricious compound. *Id.* Defendants' Contentions meet the standards set forth in the local rules.

d.) Plaintiff's Requests to Strike Various References

Plaintiff argues that Defendants' Contentions fail to provide reasonable notice as to why Defendants believe they have a reasonable chance of proving infringement.

Plaintiff takes issue with Defendants' reliance on "irrelevant marketing materials, an unrelated product (BabyDance), data from a pilot batch of BabyIt…that was never sold, and testing of an expired product and product in existence only after the patent expired." Dkt. # 102 at 6. Consequently, Plaintiff requests that all references to the aforementioned materials be stricken from Defendants' Infringement Contentions because they are not "tethered to the actual language used in the claim." *Id.* (quoting *Finjan, Inc.*, 2015 WL 1517920, at *9).

Specifically, Plaintiff objects to references to a pilot batch of BabyIt in the Contentions because it claims that pilot batch had a different formulation and different properties than other lots and was never sold. Additionally, Plaintiff objects to references to the product BabyDance, which is not alleged to practice the '509 patent claims. Finally, Plaintiffs argue that post-expiration test data on a product that appears to have expired in April 2020 (Lot 3421) and product from a lot (Lot 1789) that was manufactured in July 2020 (after the '509 patent expired in May 2020) cannot show why Defendants believe they have a reasonable chance of proving that any BabyIt lots manufactured and sold during the life of the patent actually practice the patent claims. Defendants counter that the pilot batch of BabyIt is not irrelevant because Defendants have alleged that "each BabyIt product made, used, sold and/or offered for sale" infringes the '509 patent, Dkt. # 105, Ex. A at 4, and this includes the unsold pilot batch—whether it was offered for sale or not. Regarding the references to BabyDance, a fertility lubricant, Defendants argue that the product is referenced to show that both BabyDance and BabyIt passed tests measuring sperm survival and sperm motility that suggest they are both "nonspermicidal." Dkt. # 105-2 at 6. Marketing materials—BabyIt packaging—are referenced because they state the product contains a carboner and arabinogalactan, which Defendants claim are both recited by the '509 claims. And concerning the test data references, Defendants argue that the only product available for testing was expired because Plaintiff stopped selling BabyIt in January 2020 and that

only Plaintiff is fully aware if Lot 1789 contains a different formulation and different properties than other lots.

The parties' arguments contain many accusations of what either side knows, doesn't know, should know, or only could know. The Court can only assume that these disputes will be resolved via discovery. As to Plaintiff's request to strike, the Court finds persuasive Defendants' overarching argument that the request to strike is premature because Defendants are not yet required to prove infringement at this point. Plaintiff's objections go to the substance of Defendants' Infringement Contentions, and it is not appropriate at this stage to strike various references that Plaintiff believes are not relevant. This is illustrated in the cases cited by both parties regarding the relevancy and sufficiency of testing data related to Lots 3421 and 1789.[1] In each of these cases cited by the parties, the court considered testing data of expired or differing product at the trial stage—either in the context of pre-trial motion practice or after bench trials, when the Court had the opportunity to consider all of the evidence before it and asses it in its totality—often with the benefit of expert testimony. We are simply not there yet, and the Court therefore declines to strike the various references as requested by the Plaintiff.

c.) Indirect Infringement and Doctrine of Equivalents

Plaintiff argues that Defendant's "boilerplate accusations" of indirect infringement are inadequate and that Defendants have full knowledge to make

[1] Plaintiff cites *SmithKline Beecham Corp. v. Apotex Corp.*, No. 98 C 3852, 2002 WL 1613724, at *2 (N.D. Ill. July 17, 2002) (Court granted motion in limine to exclude data obtained from expired tablets), *Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, 217 F. Supp. 3d 782, 792 (D. Del. 2016) (Court agreed with expert's conclusion at trial that "testing of the expired samples only reveals that [the relevant attribute appeared] between when it was manufactured and when it was tested"), and *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-CV-2768, 2012 WL 1080148, at *14 (E.D. Pa. Mar. 28, 2012), *aff'd*, 500 F. App'x 959 (Fed. Cir. 2013) (After trial, Court found that, given differences in particle size specification between compared products, a Canadian product was not likely to be representative of the accused product), to argue for striking references to test data, while Defendant cites *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, 265 F. Supp. 3d 490, 509 (D.N.J. 2017), *aff'd*, 747 F. App'x 852 (Fed. Cir. 2018) (Court declined to exclude testing data from expired samples of epilepsy drug when expert credibly testified that he saw no evidence of degradation or impurities that would impact the results) to argue that the testing data is relevant.

allegations of indirect infringement, because Defendants created BabyIt and would be intimately familiar with any individual or entity who were also involved in BabyIt's production. Similarly, according to Plaintiff, Defendants' Contentions allege infringement under the doctrine of equivalents with only generic, boilerplate placeholder language that does not identify aspects of specific accused lots. Defendants argue that their Contentions concerning indirect infringement meet the standards of LPR 120(d) and that if discovery reveals additional information relevant to their analysis under the doctrine of equivalents, BioOrigyn will amend their Contentions.

In their Contentions Defendants state, "Fairhaven has induced infringement of the asserted claims of the '509 Patent under 35 U.S.C. § 271(b) by directing, authorizing, encouraging, or enabling other entities, including, but not limited to, its manufacturers and authorized suppliers or distributors, to make, use, offer for sale, and/or sell the Accused Device in the United States. BioOrigyn does not presently have knowledge as to whether direct infringement of the asserted claims is based on joint acts of multiple parties." Dkt. # 105-1 at 5. This District's Local Rules require a party to describe the acts of the alleged indirect infringer that contribute to or are inducing direct infringement, and explain the role of joint or multiple parties, if known. LPR 120(d). Defendants are not required to disclose specific evidence or prove their infringement case in the Contentions, *DCG Sys. v. Checkpoint Tech., LLC*, No. C 11-03792 PSG, 2012 WL 1309161, at *2 (N.D. Cal. Apr. 16, 2012), and Defendants' Contentions put Plaintiff on notice that the alleged indirect infringement stems from the acts of "manufacturers and authorized suppliers or distributors" who "make, use, offer for sale, and/or sell" BabyIt in the United States. Dkt. # 105-1 at 5.

Regarding Defendants' doctrine of equivalents theory, their Contentions state, "…BioOriygn contends that the Accused Device embodies such claim limitation or element under the doctrine of equivalents because there are no substantial differences, and the Accused Device performs substantially the same function, in substantially the

same way, to achieve substantially the same result." *Id.* "A party asserting infringement under the doctrine of equivalents must provide specific analysis, on an element-by-element basis, as to its theory of why there is infringement under the doctrine." (*GN Resound A/S v. Callpod, Inc.,* No. C 11-04673 SBA, 2013 WL 1190651, at *6 (N.D. Cal. Mar. 21, 2013)). While Defendants indicate that Plaintiff has served no technical documents and discovery may reveal further information leading to amendment, Plaintiff's "alleged delay is beside the point," as contentions are due before discovery has taken place. *Finjan*, 2015 WL 1517920, at *10. If the party alleging infringement "does not have a factual basis to assert the doctrine of equivalents in its infringement contentions at that time, it should not do so. It is improper to assert the doctrine of equivalents with generic 'placeholder' language on the hope that future discovery might support such an assertion." *Id.* While the Court is not convinced that Defendants' Contentions must identify each lot number, *see* discussion *supra* Section III.b, the Court notes that Defendants' Contentions give little detail or specificity beyond their recitation of the standard for infringement under the doctrine of equivalents. *See Mobiloc, LLC v. Neutron Holdings, Inc.*, 555 F. Supp. 3d 1040, 1043-44 (W.D. Wash. Aug. 19, 2021) ("Equivalence may be demonstrated under… (2) the 'function-way-result' test, which asks 'whether the element of the accused device performs substantially the same function, in substantially the same way, to achieve substantially the same result, as the limitation at issue in the claim.'") (quoting *Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1015-16 (Fed. Cir. 1998)). However, "striking them will put no one any closer to resolving this case." *Recognicorp, LLC*, 2013 WL 2099518, at * 2. Defendants will have a "reasonable opportunity to verify [their] infringement allegations through discovery[,]" and will be held to the "good cause" standard for the amendment of Contentions contained in the Local Rules. Further, given that the Court declines to strike most of Defendants' Contentions, the Court also declines Plaintiff's request to stay discovery.

IV. CONCLUSION

Based on the foregoing reasons, the Court **DENIES** Plaintiff's Motion for a More Definite Disclosure of Infringement Contentions and Stay, and Motion to Strike (Dkt. # 102). Plaintiff shall serve their Non-Infringement and Invalidity Contentions within **twenty-one (21) days** of the date of this Order.

DATED this 16th day of February, 2023.

The Honorable Richard A. Jones
United States District Judge